



U.S. ENVIRONMENTAL PROTECTION AGENCY  
 Office of Pesticide Programs  
 Registration Division (7505P)  
 1200 Pennsylvania Ave., N.W.  
 Washington, D.C. 20460

**EPA Reg. Number:**

2596-163

**Date of Issuance:**

3/9/16

**NOTICE OF PESTICIDE:**

Registration  
 Reregistration

(under FIFRA, as amended)

**Term of Issuance:**

Conditional, Time-Limited  
 Expires: 03/09/2018

**Name of Pesticide Product:**

Hartz Reference #128

**Name and Address of Registrant (include ZIP Code):**

Lance Hemsarh  
 The Hartz Mountain Corporation  
 400 Plaza Drive  
 Secaucus, NJ 07094

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

**Signature of Approving Official:**

Kable Bo Davis, Product Manager 03  
 Invertebrate & Vertebrate Branch 1, Registration Division  
 (7505P)

**Date:**

3/9/16

2. This registration is time-limited and expires 03/09/2018.
3. You must submit quarterly enhanced incident reports and quarterly sales information in doses sold for this product beginning within 3 months of the date the product is first released for shipment, on the first day of the quarter (i.e., January 1, April 1, July 1, or October 1). Please flag any Confidential Business Information as such. Submit enhanced incident reporting and quarterly sales information to the Product Manager's attention. The following is a list of information that must be included in the quarterly reports for each incident:
  - EPA Registration Number
  - Product name (brand name)
  - Lot #
  - Where purchased: internet, store, veterinarian
  - Active Ingredient(s)
  - Weight range for product
  - Date on which incident occurred (mm/dd/yyyy)
  - State in which the incident occurred (standard 2 letter abbreviation)
  - Registrant case #
  - Species: dog, cat, other (specify)
  - Breed: (as reported by pet owner)
  - Age: months or years
  - Sex: M, F, or neutered
  - Weight: pounds
  - Primary Route of Exposure: dermal, oral, other animal, inhalation, other
  - Body System: neurological, dermatological, GI, respiratory, ocular, other
  - Major signs noted with separate column for each sign, using standard terminology
  - Time to Onset: (hours, days)
  - Treated by veterinarian: yes or no
  - First time product used: yes or no
  - Misuse: use on incorrect species, overdose, too frequent dosing, other (describe)
  - Any known precondition
  - EPA Severity Code: death, major, moderate, minor
  - Outcome: died, recovered, still treated, unknown
4. Along with the enhanced incident reporting, you must submit an analysis of the incidents seen, to include the following details:
  - All incidents should be reported including all minor dermal and ocular irritation reports.
  - Summary table for dogs showing number of incidents of each severity code for each route of exposure. Each incident should only be reported once. If one incident has several routes of exposure, the order should be ocular > oral > dermal. In other words, an incident with both oral and dermal exposure would be reported as oral exposure, and an incident with both ocular and oral exposure would be reported as ocular exposure.

- A similar summary table for cats (misuse or secondary exposure) showing number of incidents of each severity code for each route of exposure.
- Summary table for cats and table for dogs showing number of incidents that are believed due to secondary exposure (e.g., multi-pet households).
- A summary table for dogs showing number of incidents for each severity code for these age ranges: <3 months, 3-6 months, 6-9 months, 9-12 months, 1 yr, 2 yr, 3 yr, 4 yr, 5 yr, 6 yr, 7 yr, 8 yr, 9 yr, 10 yr, 11 yr, 12 yr, 13 yr, 14 yr, 15 yr, >15 yr.
- A summary table showing the number of dog incidents for each severity code for each pet weight range on the product label, as applicable.
- A summary table for dog weight showing number of incidents for each product weight range. This table should show number of incidents in dogs weighing less than that product weight range, number of incidents in dogs in lower half of weight range, number of incidents in dogs in upper half of weight range, and dogs weighing more than the product weight range, as applicable.
- Table showing number of incidents for each dog breed, where provided.
- Table showing number of incidents in dogs for each clinical sign.
- Table showing number of incidents in dogs for each organ system.
- Report aggregate incidents, but do not combine moderate and minor incidents.

If EPA determines that future mitigation measures are necessary for all pet spot-ons, the Agency will inform registrants. If mitigation measures are necessary, EPA may take regulatory action.

5. You are required to comply with the data requirements described in the DCI Order identified below:
  - a. Fipronil GDCI-129121-1305
  - b. Fipronil GDCI-129121-152

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: [http://www.epa.gov/oppsrrd1/contacts\\_prd.htm](http://www.epa.gov/oppsrrd1/contacts_prd.htm)

6. Make the following label changes before you release the product for shipment:
  - Revise the EPA Registration Number to read, “EPA Reg. No. 2596-163.”
7. Submit one copy of the final printed label for the record before you release the product for shipment.

Should you wish to add/retain a reference to the company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is

referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

If you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 12/31/2015

If you have any questions, you may contact Julie Breeden at 703-347-0511 or via email at [Breeden.Julie@epa.gov](mailto:Breeden.Julie@epa.gov).

Enclosure

FRONT PANEL

**Hartz® Reference # 128** [Primary Brand Name not to be used on any product labels. The word Dog will be included in all Alternate Brand Names and be at least 75% of the size of the largest letter in the product name]

Alternate Brand Names (listed at end of label)

[Included on the front panel is a clear picture of a dog in the weight range for the product]

*[Each of the above brands will be packaged in the weight classes designated below:]*

Weighing 5 to 22 lbs.

Weighing 23 to 44 lbs.

Weighing 45 to 88 lbs.

Weighing 89 to 132lbs.

ACTIVE INGREDIENTS:

Fipronil .....9.70%

OTHER INGREDIENTS ..... 90.30%

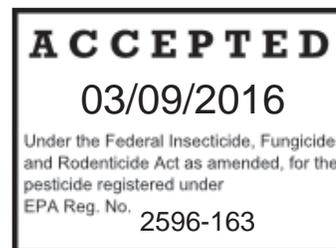
TOTAL ..... 100.00%

KEEP OUT OF REACH OF CHILDREN

CAUTION: See back panel for First Aid and additional Precautionary Statements.

NET CONTENTS:

For use ONLY on DOGS and Puppies 8 weeks and older Weighing:	Net Contents (Each tube)
5 - 22 lbs.	0.069 fl. oz. (2.01ml.), Contains 3 tubes, each 0.023 fl. oz. (0.67 ml.)
23 - 44 lbs.	0.135 fl. oz. (4.02 ml.), Contains 3 tubes, each 0.045 fl. oz. (1.34 ml.)
45 - 88 lbs.	0.273 fl. oz. (8.04 ml.), Contains 3 tubes, each 0.091 fl. oz. (2.68 ml.)
89 - 132 lbs.	0.408 fl. oz. (12.06 ml.), Contains 3 tubes, each 0.136 fl. oz. (4.02 ml.)



*[Cat Warning: A cat prohibition icon, 1.5 cm x 1.5cm, will appear on the lower right hand corner of the front panel and back panel in yellow and black images.] DO NOT USE ON CATS*

BACK PANEL

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS

CAUTION: Harmful if swallowed. Causes eye irritation. Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

### HAZARDS TO DOMESTIC ANIMALS

For external use only. Do not use on puppies under 8 weeks of age or less than 5 lbs. Sensitivities may occur after using ANY pesticide product for pets. If signs of sensitivity occur bathe your pet with mild soap and rinse with large amounts of water. If signs continue, consult a veterinarian immediately. Pets may experience some temporary irritation at the site of product application. Consult a veterinarian before using this product on medicated, debilitated or aged dogs. Call 1- 800- 275-1414 for 24-hour assistance.

### PHYSICAL OR CHEMICAL HAZARDS

**COMBUSTIBLE:** Do not use or store near heat or open flame.

### FIRST AID

**IF SWALLOWED:** Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person.

**IF IN EYES:** Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

**IF ON SKIN OR CLOTHING:** Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment or advice.

**HOT LINE NUMBER:** Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies or pesticide incidents) you may call 1-800-275-1414 twenty-four (24) hours per day, seven (7) days per week.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. Do not allow children to apply product.

### READ ENTIRE LABEL BEFORE EACH USE

USE ONLY ON DOGS OR ON PUPPIES 8 WEEKS OF AGE OR OLDER AND WEIGHING 5 LBS. OR MORE.

THIS PRODUCT CAN ONLY BE USED ON DOGS AND PUPPIES 8 WEEKS OR OLDER AND WEIGHING [Insert product weight range] INCLUDING BREEDING, PREGNANT AND LACTATING BITCHES.

### RESTRICTIONS:

DO NOT USE ON RABBITS, CATS, KITTENS, OR OTHER ANIMALS.

DO NOT EXCEED LABELED DOSAGE AMOUNT FOR DOGS.

DO NOT ALLOW YOUR DOG TO INGEST THIS PRODUCT.

*[FOR DOGS WEIGHING 89 TO 132 LBS. LABEL]*

DO NOT DOUBLE-DOSE OR APPLY MORE THAN ONE APPLICATOR TO DOGS HEAVIER THAN 132 LBS.

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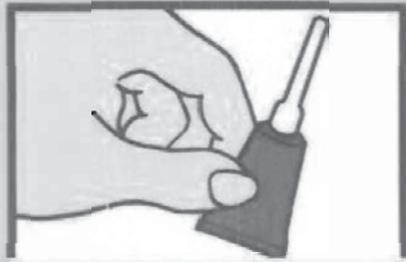
**SIDE EFFECTS**

Monitor your dog after application. Side effects may include signs of skin irritation such as redness, scratching, or other signs of discomfort. Gastrointestinal signs such as vomiting or diarrhea have also been reported. If these or other side effects occur, consult your veterinarian or call 1-800-275-1 414.

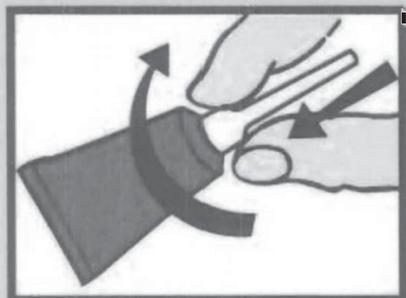


[A cat prohibition icon, 1.5 cm x 1.5 cm, will appear in a box located at the lower right hand corner of the back panel in yellow with black images.]

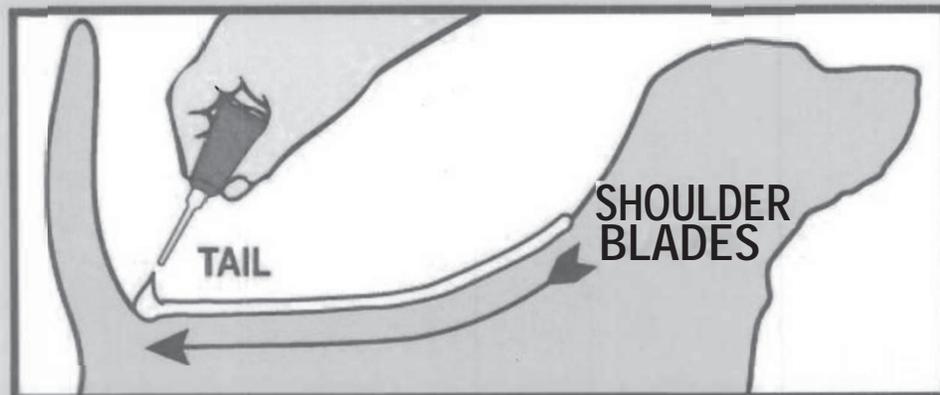
**DO NOT USE ON CATS.** Keep cats away from treated dogs for 24 hours. If applied to a cat or ingested by a cat, contact your veterinarian.



(1) Remove one applicator tube from the package and hold in an upright position pointed away from your face.



(2) Twist dispensing tip clockwise about  $\frac{1}{2}$  turn while pushing down to break the tube's seal. Do not remove the dispensing tip.



(3) Position the dispensing tip on the dog's back between the shoulder blades. Use the dispensing tip of the tube to part the dog's hair so that the product will be applied at skin level. Begin squeezing out the contents of the tube to form a stripe as you move from the shoulder blades along the dog's back to the base of the tail.

(4) Repeat every month.

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE :** Keep this product in its tightly closed original container, when not in use. Store in a cool, dry (preferably locked) area that is inaccessible to children and animals.

**PESTICIDE DISPOSAL:** Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

**CONTAINER HANDLING:** Non-refillable container. Do not reuse or refill this container. *If empty:* Place in trash or offer for recycling, if available. *If partly filled:* Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

For more information call our (flea and tick) experts at 1-800-275-1414 (weekdays, 9 am-5pm E.S.T.)

EPA Reg. No. 2596-163  
EPA Est. No. 2596-OH-1

Hartz® and other trademarks are trademarks of The Hartz Mountain Corporation.  
Made by The Hartz Mountain Corporation, 400 Plaza Drive, Secaucus, NJ 07094 (U.S.A.)  
Made in the U.S.A.

**INDIVIDUAL TUBE TEXT**

*[Product name]*

Only for use on DOGS AND PUPPIES 8 WEEKS OR OLDER

*[The appropriate size and fill volume will be correctly used on each applicable dog's weight category]*

5 to 22 lbs. - 0.023 fl. oz. (0.67 ml.),  
23 to 44 lbs. - 0.045 fl. oz. (1.34 ml.),  
45 - 88 lbs. - 0.091 fl. oz. (2.68 ml.),  
89 - 132 lbs. - 0.136 fl. oz. (4.02 ml.)

Contains fipronil (9.70%)

KEEP OUT OF REACH OF CHILDREN

CAUTION

See full label for directions for use and precautions

EPA Reg. No. 2596-163  
EPA Est. No. 2596-OH-1

*[Note: Cat Warning Icon: A cat prohibition icon will appear on the immediate container that holds the tube(s). Icon is 1.5 cm x 1.5 cm black image on a yellow background.]*

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OPTIONAL/ALTERNATE LABELTEXT

[AdultFleas]

Kills Fleas (that may transmit tapeworm) (for) (28 days) (30 days) (1 month) (4 weeks)(on dogs) Kills (Adult) Fleas (for up to 3 months)

Kills Fleas that may cause (flea allergy dermatitis) (and) (flea bite anemia) (for) (28 days) (30 days) (1 month) (4 weeks) (3 months) (on dogs)

Kills newly emerged adult Fleas before they lay eggs

If there is a high risk for flea reinfestation, a once a month application may be needed

Stops existing infestations

Prevents establishment of new infestations

Starts killing new fleas within 30 minutes\*

\*48 hours after initial application

*[Both statements must appear on the same panel. The qualifying statement is to be in close proximity with the same font, color and background with font size being 40% or greater.]*

[Ticks]

Kills Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills (all stages of ) Brown Dog Ticks, American Dog Ticks, Lone Star Ticks and Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older and weighing [Insert product weight range]

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older and weighing [Insert product weight range]

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older and [Insert product weight range]

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks)

Kills all stages of Deer Ticks that may carry Lyme disease (for) (28 days) (30 days) (1 month) (4 weeks) on dogs and puppies 8 weeks of age or older and [Insert product weight range]

Kills all biting stages of ticks

Kills adult (Brown Dog) (Deer) ticks, nymphs and larvae

Kills Ticks including those that may transmit Lyme disease

[Lice & Mange]

Rapidly eliminates chewing lice infestations

Aids in Control of sarcoptic mange infestations

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[Multiple]

Kills Fleas, Ticks, Chewing Lice,

Kills Fleas, Ticks, (through contact) (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Chewing Lice (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks, and Chewing lice through contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills Fleas, Ticks after contact (for) (28 days) (30 days) (1 month) (4 weeks)

Kills adult Fleas (for up to three months)

Kills Fleas, Brown Dog Ticks, Deer Ticks, (after contact) (for) (28 days) (30 days) (1 month)(4 weeks)

Controls Flea and Tick infestations (on dogs) (for) (28 days) (30 days) (1 month) (4 weeks)

Provides fast, effective and convenient treatment and control of fleas, ticks, chewing lice and mosquitoes (for dogs and puppies 8 weeks of age or older and weighing [Insert product weight range])

Helps prevent re-infestation of fleas and ticks (for) (28 days) (30 days) (1 month) (4 weeks)

Helps prevent flea and tick re-infestation (for) (28 days) (30 days) (1 month) (4 weeks)

[Mosquitoes]

Kills mosquitoes within 24 hours for up to 7 days, and within 48 hours for up to 28 days.

Kills Mosquitoes that may transmit West Nile virus (for) (28 days) (1 month) (4 weeks) (on dogs)

Kills Mosquitoes that may transmit heartworm (for) (28 days) (1 month) (4 weeks) (on dogs)

Controls flea and tick infestations

Once-a month Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Monthly Flea and Tick (Prevention) (Treatment) (Control) (Solution)

(28 day) (30 day) (1 month) (4 week) Flea and Tick (Prevention) (Treatment) (Control) (Solution)

Stays on and doesn't rub off

Stops and prevents infestations

Prevents re-infestation

Prevents and controls re-infestation(s)

Rapidly eliminates fleas

Fast acting

Long lasting

Effective and convenient topical treatment

Kills fleas (and ticks) through (after) contact

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(With) patented applicator  
(With) patent pending applicator  
Waterproof  
Easy spot on topical applicator  
Do not reapply product for 30 days  
Remains effective even after bathing, water immersion, or exposure to sunlight

(Product Name) remains effective even after bathing, water immersion, or exposure to sunlight.  
Effective after bathing  
Effective after exposure to water  
Avoid contact with treated area until dry.  
Can be used on breeding, pregnant and lactating bitches  
Convenient to use

Contains Fipronil. Fipronil collects in the oils of the skin and hair follicles, and continues to be released from hair follicles onto the skin and coat, resulting in long-lasting activity against fleas, ticks and chewing lice.

Patent(s) Pending Formula

Contains Fipronil (, the active ingredient used in Frontline Top Spot®).

(Brand name) is not manufactured by or distributed by Merial. Frontline Top Spot ® is a registered trademark of Merial Limited.

Only for use on dogs and puppies 8 weeks of age or older and weighing [Insert product weight range]

Formulated for dogs and puppies 8 weeks of age or older and weighing [Insert product weight range]

#### NON-PESTICIDE RELATED CLAIMS AND OTHER OPTIONAL TEXT

1st dose, 2nd dose, 3rd dose  
First month, second month, third month  
Value pack  
3 month supply  
3 monthly treatment(s)  
Convenient (easy to use) applicator  
Pro-cision Flo® Applicator  
3 Pro-cision Flo® Applicator(s) (included)

Direct to your dog's skin  
Easy (simple) to use (handle) (apply)

After application, the treated area may appear wet (or) (oily) for up to 24 hours  
You may bathe your dog 48 hours after application  
To help remind you when you last applied treatment, simply write in the date when each dose is

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Applied:  
First Dose \_\_\_\_\_  
Second Dose \_\_\_\_\_  
Third Dose \_\_\_\_\_

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Made in the U.S.A.

EPA Reg. No. 2596-163  
EPA Est. No. 2596-OH-1

ALTERNATE BRAND NAMES [Product names limited to Alternate Brand Names only. The word Dog will be included in all Alternate Brand Names and be at least 75% of the size of the largest letter in the product name.]

Hartz® UltraGuard® Flea (and) (&) Tick Topical Treatment for Dogs (&) (and Puppies)  
Hartz® InControl® Flea (and) (&) Tick Topical Treatment for Dogs (&) (and Puppies)  
Hartz® Pro Force™ Topical Treatment for Dogs (&) (and Puppies)  
Hartz® FieldForce™ Topical Treatment for Dogs (&) (and Puppies)  
Hartz® First Defense™ Topical Treatment for Dogs (&) (and Puppies)  
Hartz® UltraGuard® Flea (and) (&) Tick Topical Solution for Dogs (&) (and Puppies)  
Hartz® InControl® Flea (and) (&) Tick Topical Solution for Dogs (&) (and Puppies)  
Hartz® Pro Force™ Topical Solution for Dogs (&) (and Puppies)  
Hartz® FieldForce™ Topical Solution for Dogs (&) (and Puppies)  
Hartz® First Defense™ Topical Solution for Dogs (&) (and Puppies)

FieldForce™ Topical Treatment for Dogs (&) (and Puppies)  
First Defense™ Topical Treatment for Dogs (&) (and Puppies)  
FieldForce™ Topical Solution for Dogs (&) (and Puppies)  
First Defense™ Topical Solution for Dogs (&) (and Puppies)